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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,034

09/05/2003

James Hunter Boone

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER

CHEU, CHANGHWA J

ART UNIT

PAPER NUMBER

1641

MAIL DATE

DELIVERY MODE

01/12/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/656,034	Applicant(s) BOONE ET AL.	
	Examiner JACOB CHEU	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,7-11,13,14,17,18 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11,13,14,17,18 and 21-24 is/are rejected.
- 7) ☒ Claim(s) 1 and 7-10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/6/2009; 5/26/2009</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1641

DETAILED ACTION

Status of Claims

Applicant's amendment filed on 10/5/2009 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 2-6, 12, 15-16, 19-20 and 25 have been cancelled.
2. Claims 1, 7-11, 13-14, 17-18 and 21-24 are pending and under examination.
3. The rejection over Claims 1, 7-9, 11, 13-14, 17-18 and 21-23 under 35 U.S.C. 102(b) as being anticipated by Targan et al. (US 5750355) are withdrawn because Targan et al. do not explicitly teach using fecal samples for diagnosis of UC. Furthermore, it is not clear whether the antigen ANCA would pass through intestine wall from blood into stool and be detected.
4. A new ground of rejection is set forth in this Office Action (see below).

Claim Objections

With respect to claim 1, line 7, it is suggested that Applicant recites "wherein an elevated level of anti neutrophil cytoplasmic antibodies in indicative of ulcerative colitis".

It is also suggested Applicant placing "compared to the level of healthy control" prior to this phrase.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
2. Claims 11, 13-14, 17-18, 21-24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

Art Unit: 1641

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

As set forth in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), enablement requires that the specification teach those skilled in the art to make and use the invention without undue experimentation. Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

It is clear that the instant method is in immunological diagnosis field with an advanced knowledge in clinical diseases. With respect to claim 11, the instant claimed method directs to differentiate between ulcerative colitis (UC) and Crohn's disease (CD). The recited method is as following:

11. (Previously Presented) A diagnostic assay for differentiating between ulcerative colitis and Crohn's disease by determining whether a fecal sample contains an elevated level of anti-neutrophil cytoplasmic antibodies, the assay comprising:

obtaining a human fecal sample from a person presenting with inflammatory bowel disease;

diluting the fecal sample;

contacting the diluted sample with neutrophil cytoplasmic antigens to create a treated sample;

contacting the treated sample with polyvalent antibodies to human immunoglobulin to create a readable sample;

determining the optical density of the readable sample at 450 nm;

determining whether the optical density indicates an elevated level of anti-

Art Unit: 1641

neutrophil cytoplasmic antibodies, where an elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis.

However, in view of the clinical data, the recited method fails to satisfy enablement requirement set forth by 35 USC 112, first paragraph. Examiner would like to draw Applicant's attention to Table 2. The data do not support the assertion that a **differentiation** between UC and CD can be done simply by detection of ANCA in the fecal samples (emphasis added).

Table 2, Column 3, the UC patients have a 0.311 means of optical density of ANCA, the CD patients have a 0.209 density, whereas the healthy ones have a 0.071 density of ANCA. The last active step recites "where an elevated level of anti-neutrophil cytoplasmic antibodies is an indicator of ulcerative colitis". The results do not support such a conclusion since *both UC and CD have elevated level of ANCA* (0.311, 0.209 compared to 0.071)(emphasis added). Under this condition, one ordinary skill in the art would have no clue whether the elevated level of ANCA is attributed to CD or UC.

With respect to claim 17, the mere presence of ANCA can also be found out in the healthy people (see above).

Allowable Subject Matter

3. Claims 1, 7-10 would be allowable if rewritten or amended to overcome the objection(s) under, set forth in this Office action.
4. No claim is allowed.

Art Unit: 1641

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JACOB CHEU whose telephone number is (571)272-0814. The examiner can normally be reached on 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jacob Cheu/
Primary Examiner, Art Unit 1641

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